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Proposed Re-evaluation Decision PRVD2011-16

Ethalfluralin

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the selective preplant herbicide ethalfluralin, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing ethalfluralin for sale and use in Canada.

An evaluation of available scientific information found that products containing ethalfluralin do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of ethalfluralin uses, new risk-reduction measures are proposed to be included on the labels of all products. No additional data are being requested at this time.

This proposal affects all end-use products containing ethalfluralin registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for ethalfluralin and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of ethalfluralin.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health *and* the environment. Regulatory Directive DIR2001-03, *Pest Management Regulatory Agency Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Ethalfluralin has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

(USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 1995 RED, the USEPA concluded that ethalfluralin was eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED and in subsequent USEPA human health risk assessments published in the 2002 and 2007 Federal Register documents on ethalfluralin were an adequate basis for the proposed Canadian re-evaluation decision, with additional occupational risk assessments conducted by the PMRA during re-evaluation.

For more details on the information presented in this overview, please refer to the Science Evaluation of this consultation document.

What Is Ethalfluralin?

Ethalfluralin is a selective preplant soil incorporated herbicide for preemergence control of volunteer cereal, annual grass and broadleaved weeds. The herbicidal activity of ethalfluralin is due to inhibition of cell division. It is registered for use on canola, field peas, yellow mustard, sunflowers, alfalfa (for establishment), coriander, fababeans, soybeans, dry common beans (white and kidney), dill, caraway, safflower, and lentils. Ethalfluralin is applied once per year, either in the fall or in the spring prior to seeding, followed by two soil incorporations with tractor-drawn equipment. The first soil incorporation must be done within 24 hours of application and preferably simultaneously with application. The granular ethalfluralin end-use product can be applied by farm workers or custom applicators using a granular spreader. In addition, ethalfluralin can be applied by custom applicators as a blended liquid or granular fertilizer-pesticide product using groundboom equipment or granular application equipment, respectively.

Health Considerations

Can Approved Uses of Ethalfluralin Affect Human Health?

Ethalfluralin is unlikely to affect your health provided that proposed mitigation measures are followed.

People could be exposed to ethalfluralin by consuming food and water, through ambient air, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Ethalfluralin is unlikely to affect human health provided that risk-reduction measures proposed by the PMRA to further protect workers are implemented.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Ethalfluralin is currently registered in Canada for use on canola, field peas, yellow mustard, sunflowers, alfalfa establishment, coriander, fababeans, soybeans, dry common beans (white and kidney), dill, caraway, safflower, and lentils and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for ethalfluralin in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL will be implemented in the future, as indicated in the December 2009 Information Note, *Progress on Minimizing Reliance on the 0.1 Parts per Million as a General Maximum Residue Limit for Food Pesticide Residue*.

Environmental Considerations

What Happens When Ethalfluralin Is Introduced Into the Environment?

Ethalfluralin is unlikely to affect non-target organisms provided that proposed mitigation measures are followed.

Terrestrial and aquatic species could be exposed to ethalfluralin in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated

environmental concentration to the relevant effects endpoint of concern. In this screening level assessment, the resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some potential risks of concern.

Ethalfluralin is unlikely to pose adverse effects to the environment if used according to amended labels. The PMRA proposes improvements to environmental label statements and that the manufacturing concentrate label includes instructions to applicators that blended fertilizer be incorporated into soil following application. Furthermore, the PMRA will require aquatic and terrestrial buffer zones for blended liquid fertilizer-pesticide products containing ethalfluralin to protect aquatic organisms and terrestrial plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of ethalfluralin, the PMRA is proposing further risk-reduction measures for ethalfluralin products.

- Hazard label statements regarding the skin sensitization and eye and skin irritation potential.
- Additional personal protective equipment (PPE) and engineering controls for workers.
- A 24-hour restricted-entry interval (REI).
- Improvements to environmental label statements.
- Buffer zones for application of liquid blended fertilizers to protect non-target, sensitive aquatic and terrestrial habitats.
- Addition of use instructions for ethalfluralin blended fertilizers to the manufacturing concentrate label, including the requirement for soil incorporation.
- Requirement for the fertilizer blending facilities to provide the ethalfluralin manufacturing concentrate label to the custom applicator of ethalfluralin blended fertilizers.

A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

Next Steps

Before making a final re-evaluation decision on ethalfluralin, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

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2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Ethalfluralin is a selective preplant soil incorporated herbicide. It belongs to the dinitroaniline chemical family and is classified as a Group 3 herbicide. The herbicidal activity of ethalfluralin is due to inhibition of cell division.

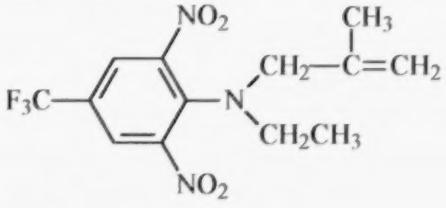
Following the re-evaluation announcement for ethalfluralin, the registrant of the technical grade active ingredient (TGAI) in Canada indicated that they intended to provide continued support for all uses in Canada, with the exception of the use on triazine tolerant canola.

The Pest Management Regulatory Agency (PMRA) used the most recent assessments of ethalfluralin from the United States Environmental Protection Agency (USEPA) and conducted additional occupational risk assessments during re-evaluation. The USEPA Reregistration Eligibility Decision (RED) document for ethalfluralin, dated March 1995 (Document ID: EPA-HQ-OPP-2009-0081-0010) and the USEPA Federal Register documents from 2002 and 2007 (final rule) and related documents as well as other information on the regulatory status of ethalfluralin in the United States (Docket ID: EPA-HQ-OPP-2005-0195) can be found on the US federal government regulations database at www.regulations.gov.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity

Identity of the Technical Grade Active Ingredient

Common name	Ethalfluralin
Function	Herbicide
Chemical family	Dinitroaniline
Chemical name	
1 **International Union of Pure and Applied Chemistry (IUPAC)**	N-ethyl-α,α,α-trifluoro-N-(2-methylalyl)-2,6-dinitro-p-toluidine
2 **Chemical Abstracts Service (CAS)**	N-ethyl-n-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine
CAS Registry Number	055283-68-6
Molecular formula	$C_{13}H_{14}F_3N_3O_4$
Structural formula	
Molecular weight	333.3 amu

Based on the manufacturing process used, contaminants of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties

Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 25°C	11.7 mPa
UV–visible spectrum	λ_{max}(nm) Absorbance 203 1.4 268.4 0.6 Expected to absorb at λ_{max} 350nm
Solubility in water at 25°C	0.3 mg/L
***n*-Octanol–water partition coefficient at 25°C**	pH log K_{ow} 7 5.11
Dissociation constant	Not applicable, does not dissociate in water

2.3 Comparison of Use Patterns in Canada and the United States

Ethalfluralin is a selective preplant soil incorporated herbicide for preemergence control of volunteer cereal, annual grass and broadleaved weeds. It is registered for use on canola, field peas, yellow mustard, sunflowers, alfalfa establishment, coriander, fababeans, soybeans, dry common beans (white and kidney), dill, caraway, safflower, and lentils. Products currently registered in Canada include one Technical Grade Active Ingredient, one Commercial Class end-use product formulated as granules, and one Manufacturing Concentrate that is used solely in the manufacture of granular or liquid customer-formula fertilizer-pesticide products (blended fertilizers) regulated under the *Fertilizers Act*.

Ethalfluralin products are applied once per year at a maximum rate of 1.44 kg a.i./ha, either in the fall or in the spring prior to seeding, using a granular spreader (granular end-use product and granular blended fertilizers) or by groundboom application (liquid blended fertilizers), followed by two soil incorporations with tractor-drawn equipment. The first incorporation is done within 24 hours of application and preferably simultaneously with application. The second incorporation is done at least three days following the first incorporation of the end-use product, and at least six days following the first incorporation of the blended fertilizers.

The American and Canadian use patterns were compared. The Canadian use-sites, formulations, application method and application rates are encompassed by those assessed in the United States with the exception of use on lentils, caraway and coriander. The PMRA determined that the USEPA RED and the Federal Register Documents for ethalfluralin are an adequate basis for the re-evaluation of all uses of ethalfluralin in Canada, including the Canadian-specific uses, with additional occupational risk assessments conducted by the PMRA during re-evaluation.

All current uses, except for use on triazine tolerant canola, are being supported by the registrant and were, therefore, considered in the re-evaluation of ethalfluralin. The use on triazine-tolerant canola will be removed from the label. Appendix I lists all ethalfluralin products that are registered as of 16 June 2011, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 1995 RED, the USEPA concluded that the use of end-use products containing ethalfluralin would not pose unreasonable risks or adverse effects to humans or the environment if products were used according to the amended product labels. In 2002 and 2007, Federal Register documents were published establishing tolerances for residues of ethalfluralin in or on several food commodities. Based on 2002 and 2007 aggregate risk assessments under the *Food Quality Protection Act* (FQPA), the USEPA concluded that aggregate exposure to ethalfluralin residues will result in no harm to the general population and to infants and children.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to ethalfluralin may occur through consumption of food and water, through ambient air, while working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

The toxicological endpoints for assessing risk to human health are summarized in Appendix II.

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This factor should take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children and potential pre- and post-natal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

The data used by the USEPA regarding reproductive and developmental toxicity for ethalfluralin is sufficiently complete for hazard characterization. With respect to potential pre- and post-natal toxicity, sensitivity of the young was observed in the rabbit developmental toxicity studies. A slight increase in resorptions as well as increased incidences of sternal and cranial variations were observed in fetuses in the presence of maternal toxicity.

The database used by the USEPA is sufficient to characterize the toxicity to infants and children from exposure to ethalfluralin. Although the fetal effects observed in the rabbit developmental toxicity assays were considered serious endpoints, the concern for post-natal toxicity was tempered by the presence of maternal toxicity. Therefore, the PCPA factor has been reduced to 3-fold when using the rabbit developmental toxicity assay to establish the point of departure for women of child bearing age.

Consequently, the PMRA determined that a PCPA factor of 3 should be used in place of the FQPA safety factor of 1 used by the USEPA in assessment of ethalfluralin exposure scenarios when the rabbit developmental toxicity study is used to establish the endpoint for women of child bearing age. The use of a PCPA factor of 3 results in a lower acute reference dose (ARfD) used by the PMRA for the acute dietary risk assessment in comparison to the USEPA's reference dose (aPAD).

No toxicological endpoint was selected by the USEPA for the assessment of short-term dermal exposure because no systemic effects were observed in a dermal study. However, the PMRA determined that short-term dermal exposure of workers can be assessed using the oral endpoint from the rabbit developmental toxicity study with a target MOE of 300 (10-fold for interspecies extrapolation, 10-fold for intraspecies variability, and 3-fold to address the concern for pregnant workers).

Ethalfluralin was classified as a possible human carcinogen (Group C) by the USEPA Cancer Peer Review Committee, which recommended using the Q_1* approach to assess the cancer risk associated with use of ethalfluralin.

Ethalfluralin was found to be a skin sensitizer, consequently, a precautionary label statement regarding the skin sensitization potential is proposed by the PMRA to be included on all ethalfluralin labels. Furthermore, based on the eye and skin irritation potential of the technical grade ethalfluralin, the PMRA proposes appropriate acute toxicity hazard label statements and precautionary statements to be included on the technical grade and manufacturing concentrate labels. Based on the eye irritation potential, protective eyewear is proposed for all workers. The proposed label amendments are listed in Appendix III.

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

Ethalfluralin was classified as a possible human carcinogen (Group C) by the USEPA. In the case where evidence of carcinogenicity is identified for the active ingredient, a cancer potency factor (Q_1*) is generated and used to estimate cancer risk. The product of the expected exposure and the cancer potency factor (Q_1*) estimates the lifetime cancer risk as a probability. A lifetime cancer risk of 1 in 10^{-5} in worker populations is generally considered acceptable.

3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

Based on the current use pattern, the PMRA determined that there is potential for short-term dermal and inhalation exposure of workers applying the granular end-use product and workers applying granular or liquid blended fertilizers containing ethalfluralin.

Blended fertilizer products, subject to regulation under the *Fertilizers Act*, are formulated by mixing the ethalfluralin manufacturing concentrate with the fertilizer component in a commercial facility using a closed system. The blending facility worker delivers the blended fertilizer to the application site and transfers it to application equipment using a closed transfer system. The occupational exposure of workers handling the manufacturing concentrate in commercial facilities is not discussed in this document since the manufacture of blended fertilizers in commercial facilities and proper use and safe disposal of fertilizer products are controlled by provincial rules and regulations.

The PMRA assessed the following potential occupational exposure scenarios:

- A farm worker or a custom applicator loading and applying the granular end-use product using a solid broadcast spreader.
- A custom applicator applying a granular blended fertilizer using a solid broadcast spreader.
- A custom applicator applying a liquid blended fertilizer using groundboom equipment.

Short-term dermal and inhalation exposures of workers were assessed by the PMRA using unit exposure values from the Canadian Pesticide Handlers Exposure Database (PHED) tables, the maximum application rate of 1.44 kg a.i./ha, and an area treated per day up to 360 ha. Additional assumptions included: different levels of personal protective equipment (PPE) and engineering controls, a dermal absorption factor of 100 %, an inhalation absorption factor of 100 %, and a default worker body weight of 70 kg.

To estimate the cancer risk for workers, a lifetime average daily dose (LADD) was calculated and then multiplied by the cancer potency factor of 8.9×10^{-2} $(mg/kg\text{-}bw/day)^{-1}$. LADD values were calculated based on an absorbed daily dose (with a dermal absorption factor of 2.8% and assuming an area treated per day up to 240 ha) and assuming 15 and 30 days exposure for farmers and custom applicators, respectively, a working lifetime of 40 years, and a lifespan of 75 years.

The PMRA determined that exposure of workers to ethalfluralin results in acceptable non-cancer and cancer risk when workers wear coveralls over a single layer of clothing and gloves during all activities plus a NIOSH-approved respirator while loading. A NIOSH-approved respirator or a closed cab is also required during application if handling more than 110 kg a.i./day.

Consequently, based on the risk assessments and the eye irritation potential of ethalfluralin, the PMRA proposes the following mitigation measures to further protect workers:

- PPE consisting of coveralls over a long-sleeved shirt and long pants, protective eyewear and chemical-resistant gloves for all workers;
- A NIOSH-approved respirator while loading;
- A NIOSH-approved respirator or a closed cab while applying, when handling more than 110 kg a.i./day (76 ha at the maximum rate of 1.44 kg a.i./ha).

The proposed label amendments are listed in Appendix III.

3.1.1.2 Postapplication Exposure and Risk

The postapplication occupational risk assessment considers exposures to workers entering treated sites. The PMRA determined that postapplication exposure of workers entering treated sites is expected to be negligible because ethalfluralin will be soil-incorporated following the application.

A 24 hour restricted-entry interval (REI) is proposed by the PMRA, based on the eye and skin irritation potential of ethalfluralin, for all workers except for those entering treated sites for the purpose of soil incorporation.

Proposed label amendments are listed in Appendix III.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

There are no residential uses of ethalfluralin registered in Canada; therefore residential handler exposure to ethalfluralin is not expected.

Ethalfluralin has been detected by Environment Canada in air monitoring samples in the prairie regions of Canada. The PMRA evaluated these data to ensure health risks to bystanders are not of concern. The PMRA used maximum air concentrations to assess short-term inhalation bystander exposure of toddlers, youths, and adults based on default inhalation rates, outdoor exposure time, and default body weights. The non-cancer MOEs are above the target MOE of 100 and the cancer risks are below 1×10^{-6}, and therefore, are not of concern. Based on this, the PMRA requires no further mitigation measures with respect to bystander exposure.

3.1.2.2 Exposure from Food and Drinking Water

There are no Canadian maximum residue limits (MRLs) established for ethalfluralin. Where no specific MRL for a pest control product has been established in the Food and Drug Regulations, subsection B.15.002(1) applies. This requires that residues do not exceed 0.1 ppm and has been considered a general MRL for enforcement purposes. Currently, residues of ethalfluralin in all agricultural commodities, including those approved for treatment in Canada are regulated by subsection B.15.002(1). However, changes to this general MRL will be implemented in the future, as indicated in the December 2009 Information Note, *Progress on Minimizing Reliance on the 0.1 Parts per Million as a General Maximum Residue Limit for Food Pesticide Residue*.

In their 2007 dietary risk assessment, the USEPA conducted ethalfluralin acute and chronic (non-cancer and cancer) dietary (food plus water) exposure and risk assessments, based on the assumption that 100 % of each crop is treated. The acute and chronic non-cancer assessments were conducted using a combination of anticipated residue values based on field trials and tolerance-level and proposed tolerance-level residue values for food commodities, and estimated drinking water concentrations. The cancer assessment was refined further by using monitoring data and field trial data to set anticipated residue values for selected commodities, and by using drinking water monitoring studies to set the anticipated residue value for drinking water.

Acute and Chronic Dietary Non-Cancer Risk

Acute dietary risk is calculated considering the highest ingestion of ethalfluralin that would be likely on any one day, and using food consumption and food residue values. A statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of ethalfluralin residue that might be consumed in a day. A value representing the high end (95th percentile) of this distribution is compared to the acute reference dose, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the acute reference dose, then acute dietary exposure is considered acceptable.

For females, ages 13-49, the USEPA acute dietary (food plus water) risk assessment was based on an acute population adjusted dose (aPAD) of 0.75 mg/kg bw/day, derived from a NOAEL of 75 mg/kg bw/day from a developmental toxicity study in rabbits. For all supported and proposed commodities, the acute dietary risk estimate was <1 % of the aPAD, therefore not of concern. The use of a PCPA factor of 3 resulted in a lower acute reference dose (ARfD) for the acute dietary risk assessment in comparison to the USEPA's reference dose. However, the PMRA determined the USEPA conclusions regarding acute dietary exposure are relevant to the Canadian situation because the exposure estimates remain well below 100% of the ARfD. Chronic dietary risk is estimated by determining how much of a pesticide residue may be ingested with the daily diet and comparing this potential exposure to an acceptable daily intake, which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. The acceptable daily intake is referred to as the ADI in Canada, and, in the USEPA 2007 dietary risk assessment, it is expressed as the chronic population adjusted dose (cPAD). The ADI is based on a relevant endpoint from toxicology studies and on uncertainty factors protective of the most sensitive subpopulation (see Appendix II).

The chronic dietary assessment for all populations was based on a cPAD of 0.04 mg/kg bw/day derived from a NOAEL of 4 mg/kg bw/day from a one year chronic oral toxicity study in dogs. For all supported and proposed commodities, and all population subgroups, the chronic dietary (food plus water) risk estimate was <1 % of the cPAD, and therefore not of concern.

Dietary Cancer Risk

When evidence of carcinogenicity is identified for the active ingredient, a cancer potency factor (Q_1^*) is generated and used to estimate cancer risk. The product of the expected exposure and the cancer potency factor (Q_1^*) estimates the lifetime cancer risk as a probability. A lifetime cancer risk below 1×10^{-6} usually does not indicate an unacceptable risk for the general population when exposure occurs through pesticide residues in or on food and to otherwise unintentionally exposed persons.

Ethalfluralin is classified as a possible human carcinogen with a Q_1^* of 8.9×10^{-2} $(mg/kg/day)^{-1}$. The chronic cancer dietary risk (food plus water) estimate for the general American population was 2×10^{-6}.

This lifetime cancer risk estimate from exposure to ethalfluralin in food and water exceeds the PMRA level of concern of 1×10^{-6}. However, taking into consideration conservative assumptions used in the US assessment (100% of all crops for which ethalfluralin is registered are treated) and use information in Canada, the PMRA concluded that the cancer risk is likely to be overestimated. Furthermore, available Canadian water monitoring data for ethalfluralin indicate that the levels of ethalfluralin in Canadian drinking water sources are lower than the drinking water levels of ethalfluralin used in the US dietary risk assessments. Further, the Canadian specific uses (coriander, caraway, and mustard) are not expected to contribute significantly to dietary exposure. Overall, the PMRA concluded that the cancer risk for dietary exposure of the Canadian population is of no concern.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to ethalfluralin. Risk from aggregate exposure to ethalfluralin is expected from food, drinking water and ambient air (i.e. bystander inhalation exposure) only. Risk from exposure to ethalfluralin through food and drinking water is not of concern, and based on the very low non-cancer and cancer risks to the general population from bystander inhalation exposure, the ambient air is not expected to significantly contribute to aggregate exposure. On this basis, the PMRA concludes that the aggregate risk is not of concern and no mitigation measures are proposed.

3.1.3 Cumulative Effects

The USEPA has not determined whether ethalfluralin has a common mechanism of toxicity with other substances, although they have determined that it does not belong in the four groups of pesticides for which cumulative risk assessments have been deemed necessary. The USEPA has determined that ethalfluralin does not appear to produce a toxic metabolite produced by other substances. Therefore, it was assumed that ethalfluralin does not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required by the USEPA.

3.2 Environment

3.2.1 Environmental Risk Assessment

The USEPA determined that ethalfluralin is not expected to persist in the environment (half-life in soil $\leq$ 46 days); has a moderate potential for bioconcentration (BCF 860- to 1520-fold); and is not expected to reach ground water but may reach surface water on eroded soil particles.

Based on acute toxicity studies, the USEPA determined that technical grade ethalfluralin is practically non-toxic to avian species and honeybees, slightly toxic to practically non-toxic to small mammals, and highly to very highly toxic to freshwater fish and invertebrates and estuarine/marine organisms.

To assess the ecological risk of ethalfluralin to both terrestrial and aquatic non-target plants and animals, the USEPA calculated risk quotients (RQs) based on appropriate toxicity endpoints and expected environmental concentrations (EECs) and compared the resulting RQs to corresponding levels of concern (LOCs).

The USEPA determined that for incorporated granular or liquid formulations applied at a rate of 1.9 kg a.i./ha, the calculated acute and chronic RQs were below the LOCs for birds, terrestrial and semi-aquatic plants, and marine/estuarine and freshwater invertebrates and fish.

The USEPA determined that minimal risk is expected for mammals and insects based on low toxicity of ethalfluralin to these species. For aquatic plants, risk is not expected since expected aquatic residues are below the established level of concern. Overall, the potential for ethalfluralin to have adverse effects on mammals, insects and aquatic plants was expected to be low.

The USEPA assessment is relevant to the Canadian situation. Aquatic and terrestrial buffer zones for liquid blended fertilizers were calculated by the PMRA to minimize spray drift to non-target species during ground application. The PMRA will require terrestrial and aquatic buffer zones of 1 to 10 meters to protect aquatic organisms and terrestrial plants from spray drift during application of liquid blended fertilizers. Proposed label amendments are listed in Appendix III. Inputs to buffer zone models are described in Appendix IV. Improvements to the environmental label statements regarding toxicity to aquatic species and control of run-off are proposed by the PMRA. In addition, the PMRA proposes that the manufacturing concentrate label includes instructions to applicators that blended fertilizer be incorporated into soil following application. The proposed label amendments are listed in Appendix III.

3.3 Pest Control Product Policy Considerations

3.3.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the re-evaluation process, ethalfluralin was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

Ethalfluralin does not meet all the Track 1 criteria and therefore is not considered a Track 1 substance. The soil and water half-lives of ethalfluralin are less than the TSMP persistence criterion of 182 days (aerobic soil half-life of 46 days, anaerobic soil half-life of 14 days, photodegradation water half-life of 6.3 hours, and anaerobic water half-life of 38 hours). Ethalfluralin has a moderate potential for bioaccumulation. The log K_{ow} of 5.11 indicates potential for bioaccumulation, however, the bioconcentration factors in fish (860–1520X) are below the TSMP criterion (bioconcentration factor $\geq$5000).

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of ethalfluralin, contaminants in the technical are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

Technical grade ethalfluralin does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

3.3.3 Other Contaminants of Toxicological Concern

During the review process, the potential presence of impurities known to have, or suspected to have, health and/or environmental implications are assessed in accordance with DIR98-04.

4.0 Incident reports

Starting 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

There were no incident reports submitted to the PMRA database for ethalfluralin at the time of re-evaluation.

5.0 Organisation for Economic Co-operation and Development Status of Ethalfluralin

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 33 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Based on the current available information on the status of ethalfluralin in other OECD member countries, ethalfluralin is not authorized for use in the European Union, as the registrants withdrew their support for its inclusion in Annex I to Directive 91/414/EEC. Ethalfluralin is not registered for use in Australia or New Zealand.

As described earlier in this document, the United States, also an OECD member, assessed the registration of all uses of ethalfluralin in 1995 and concluded using ethalfluralin as a pesticide does not result in unreasonable adverse effects to human health or the environment provided the risk-reduction measures recommended in the RED document were implemented.

The Canadian re-evaluation of ethalfluralin is based in part on the 1995 and 2007 USEPA assessments and included occupational risk assessments conducted by the PMRA during re-evaluation. Based on the re-evaluation, the PMRA concluded that additional mitigation measures are required to further protect the human health and the environment.

6.0 Proposed Re-evaluation Decision

The PMRA is proposing continued registration of products containing ethalfluralin for sale and use in Canada with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment:

- Hazard label statements regarding the skin sensitization and eye and skin irritation potential.
- Additional PPE and engineering controls for workers.
- A 24-hour REI.
- Improvements to environmental label statements.
- Addition of use instructions for ethalfluralin blended fertilizers to the manufacturing concentrate label, including the requirement for soil incorporation.
- Buffer zones for application of liquid blended fertilizers to protect non-target, sensitive aquatic and terrestrial habitats.
- Requirement for the fertilizer blending facilities to provide the ethalfluralin manufacturing concentrate label to the custom applicator of ethalfluralin blended fertilizers.

The labels of the Canadian technical grade, manufacturing concentrate and end-use products must be amended to include label statements listed in Appendix III. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. No additional data are being requested at this time.

7.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, *Pest Management Regulatory Agency Re-evaluation Program,* and DACO tables can be found on the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at http://www.ec.gc.ca/toxiques-toxics/.

The USEPA RED document for ethalfluralin is available at www.regulations.gov (Docket ID EPA-HQ-OPP-2005-0195).

The European Union's Commission Decision on ethalfluralin, 2008/934/EC, is available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:333:0011:0014:EN:PDF.

List of Abbreviations

ADI	acceptable daily intake
a.i.	active ingredient
amu	atomic mass unit
aPAD	acute population adjusted dose
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstracts Service
CFIA	Canadian Food Inspection Agency
cPAD	chronic population adjusted dose
EEC	expected environmental concentration
FQPA	*Food Quality Protection Act*
g	gram(s)
ha	hectare
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LOAEL	lowest observed adverse effect level
LOC	level of concern
mg	milligram(s)
MOE	margin of exposure
mPa	millipascal
MRL	maximum residue limit
nm	nanometre
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PCPA	*Pest Control Products Act*
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
Q_1^*	cancer potency factor
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
RQ	risk quotient
SF	safety factor
UF	uncertainty factor
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Registered Products Containing Ethalfluralin as of 16 June 2011

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
20980	Commercial	Dow AgroSciences Canada Inc.	Edge Granular Herbicide	Granular	5% w/w
20055	Technical	Dow AgroSciences Canada Inc.	Ethalfluralin Technical Herbicide	Solid	96% w/w
21012	Manufacturing Concentrate	Dow AgroSciences Canada Inc.	Ethalfluralin Manufacturing Concentrate	Emulsifiable concentrate or emulsion	360 g/L

Appendix II Toxicological Endpoints for Ethalfluralin Health Risk Assessments

Exposure Scenario (route and period of exposure)	Dose (mg/kg bw/day)	Study	UF/SF or MOE[a]
Acute dietary (general population, including infants and children)	A single dose effect relevant to the general US population including infants and children was not identified in the toxicity studies conducted with ethalfluralin		
Acute dietary (females 13-49 years of age)	NOAEL = 75 aPAD[b] = 0.75	Rabbit Developmental Toxicity Study; LOAEL = 150 mg/kg bw/day based on increased number of resorptions and increased sternal and cranial variations	UF = 100 PCPA factor = 3[d]
Chronic dietary (all populations)	NOAEL = 4 cPAD[c] = 0.04	Dog 1 year chronic oral toxicity study; LOAEL = 20 mg/kg bw/ day based on altered red blood cell morphology and urinary bilirubin	UF= 100
Cancer (oral, dermal, inhalation)	Q_1^* = 8.9×10^{-2} (mg/kg bw/day)$^{-1}$ For the dermal route, a dermal absorption factor of 2.8 % was used (based on a rhesus monkey study).	Rat two year chronic/carcinogenicity study Based on increased mammary gland fibroadenomas and combined adenomas/fibro-adenomas in female rats.	
Short-term dermal (1-30 days)	NOAEL = 75 Assume dermal absorption factor of 100 %	Rabbit Developmental Toxicity Study; LOAEL = 150 mg/kg bw/day based on increased number of resorptions and increased sternal and cranial variations	MOE = 300[e]
Short-term Inhalation (1-30 days)	NOAEL = 12.5 Inhalation absorption assumed to be 100 % for oral to inhalation route extrapolation.	Three-generation reproduction study in rats (oral); LOAEL = 37.5 mg/kg bw/day based on decreased body weight gains in males in all generations.	MOE = 100

NOAEL - no observed adverse effects level; LOAEL = lowest observed adverse effects level; PCPA Factor = Pest Control Products Act Factor; Q_1^* = cancer potency factor

a UF/SF refers to total of uncertainty or PCPA factors for dietary assessments, MOE refers to desired margin of exposure for occupational or residential assessments. Where UF = 100: 10-fold for interspecies extrapolation; 10-fold for intraspecies variability.

b aPAD is the acute population adjusted dose, the reference dose used in the USEPA acute dietary risk assessment.

c cPAD is the chronic population adjusted dose, the reference dose used in the USEPA chronic dietary risk assessment.

d The use of the PCPA factor of 3 results in an acute reference dose (ARfD) of 0.25. ARfD is the reference dose used by the PMRA for acute dietary risk assessments. See Section 3.1 for details.

e MOE includes a factor of 3-fold to address the concern for pregnant workers. See Section 3.1 for details.

Appendix III Label Amendments for Products Containing Ethalfluralin

The label amendments presented below do not include all label requirements for individual products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

TECHNICAL GRADE PRODUCT LABEL (Registration No. 20055)

I) The following statements must be included on the primary panel on the technical grade product label:

POTENTIAL SKIN SENSITIZER
DANGER - EYE AND SKIN IRRITANT

II) The following statements must be included in a section entitled **PRECAUTIONS** on the technical grade product label:

Potential skin sensitizer.
Causes eye and skin irritation. DO NOT get in eyes or on skin.

END-USE PRODUCT LABEL (Registration No. 20980)

I) The following use-site must be removed from a section entitled **CROPS REGISTERED** on the end-use product label:

triazine tolerant canola

II) The following statement must be included on the primary panel:

POTENTIAL SKIN SENSITIZER

III) The following statements must be included in a section entitled **PRECAUTIONS** on the end-use product label:

Potential skin sensitizer.

Wear coveralls over a long-sleeved shirt and long pants, chemical resistant gloves and protective eyewear during all activities plus a respirator with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH/MSHA/BHSE approved canister approved for pesticides while loading. In addition, when handling more than 2200 kg of Edge Granular per day (110 kg a.i./day; 78 ha at the maximum rate of 1.4 kg a.i./ha), wear a respirator as specified above while applying or use a closed cab while applying.

DO NOT enter treated areas for 24 hours following application unless it is for soil incorporation.

IV) The following statements must be included in a section entitled **DIRECTIONS FOR USE** on the end-use product label:

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests. DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

V) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARD** on the end-use product label:

Toxic to aquatic organisms.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

MANUFACTURING CONCENTRATE PRODUCT LABEL (Registration No. 21012)

I) The following hazard label statements must be included on the primary panel on the manufacturing concentrate product label:

POTENTIAL SKIN SENSITIZER
DANGER - EYE AND SKIN IRRITANT

II) The following statements must be included in a section entitled **PRECAUTIONS** on the manufacturing concentrate product label:

> Potential skin sensitizer.
> Causes eye and skin irritation. DO NOT get in eyes or on skin.
>
> Wear protective eyewear.

III) The following statement must be included in the section entitled **MANUFACTURING INSTRUCTIONS, DIRECTIONS FOR USE** on the manufacturing concentrate label after the statement "The blended fertilizer is to be custom applied.":

> The manufacturer of the blended fertilizer must provide a copy of this label to the custom applicator to provide them with use instructions and precautions for application of the blended fertilizer containing ethalfluralin.

IV) The section entitled **APPLICATION** on the manufacturing concentrate label should be renamed: **APPLICATION OF BLENDED FERTILIZERS - USE INFORMATION TO BE COMMUNICATED TO CUSTOM APPLICATOR.** The following detailed information must be included in this section:

> PRECAUTIONS including hazard statements, personal protective equipment required for applicators of ethalfluralin blended fertilizer, REI.
>
> DIRECTIONS FOR USE including weeds controlled, weeds suppressed, crops registered and application instructions for custom applicators of granular and liquid blended fertilizer.
>
> ENVIRONMENTAL HAZARD statements.

Within those sections, the following statements must be included:

> Potential skin sensitizer.
>
> Wear coveralls over a long-sleeved shirt and long pants, chemical resistant gloves and protective eyewear during all activities plus a respirator with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH/MSHA/BHSE approved canister approved for pesticides while loading (unless a closed transfer system was used for loading). In addition, when handling more than 110 kg a.i./day (76 ha at the maximum rate of 1.44 kg a.i./ha), wear a respirator as specified above while applying or use a closed cab while applying.

Apply to a soil surface free of large clods and incorporate in the same operation if possible. The first incorporation must be done within 24 hours of application.

DO NOT enter treated areas for 24 hours following application unless it is for soil incorporation.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer zones for liquid blended fertilizer application:

Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer or spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublandds), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	**Crop**	**Buffer Zones (metres) Required for the Protection of:**				
		Freshwater Habitat of Depths:		**Estuarine/Marine Habitats of Depths:**		**Terrestrial Habitat**
		Less than 1m	**Greater than 1m**	**Less than 1m**	**Greater than 1m**	
Field sprayer	Western and eastern Canadian crops	10	1	1	1	1

TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

DO NOT use to control aquatic pests. DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

V) The statement for custom applicator must be replaced with the following to indicate that all use information can be found on the manufacturing concentrate label instead of the information sheet.

NOTE: Custom applicator must provide the grower with proper use information. Follow the manufacturing concentrate label for ethalfluralin blended fertilizer for all claims, uses and management of the end use formulated product. Failure to follow the manufacturing concentrate label for ethalfluralin blended fertilizer may result in erratic weed control and/or crop damage.

Appendix IV Inputs to Buffer Zone Models

Table 1 Ground Use Data (from Canadian labels)

Crop	Formulation Type	Method of Application	Number of Application	Maximum Application Rate (g a.i./ha)
Western Canadian crops	Liquid	Ground boom	1	1440
Eastern Canadian crops	Liquid	Ground boom	1	1080

Table 2 Model Input Data for Aquatic and Terrestrial Buffer Zones (from 1995 RED)

Half-life for aquatic buffer zones	Aerobic whole system DT_{50} = 1.6 day
Most sensitive fish endpoint for amphibian risk assessment	Bluegill sunfish Acute 1/10 LC_{50} = 0.0032 mg/L
Most sensitive freshwater species	Bluegill sunfish Acute 1/10 LC_{50} = 0.0032 mg/L
Most sensitive estuarine/marine species	Eastern Oyster ½ LC_{50} = 0.05 mg/L
Half-life for terrestrial buffer zones	In the absence of data, assumed to be stable for seedling emergence endpoint.
Most sensitive terrestrial plant species	Sorghum and wheat EC_{25} = 112.4 g/ha – seedling emergence

References

Studies considered in the Chemistry Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1802724	1995, EFR-FHM-1 Quality Control Methods Analysis for 10 Consecutive Industrial Batches for Technical Ethalfluralin, DACO: 2.13.3
1851771	DACO: 2.0_Re-Eval
1802728	1995, EFR-FHM-1 Analytical Data and Methodology. Preliminary Analysis of Product Sample for Active Ingredient and Impurities Present in Ethalfluralin Technical. Included in Appendix I Analysis of product sample for impurities, Appendix II Comparability of Finchimca and ChemService Studies. DACO 2.13.4

B. ADDITIONAL INFORMATION CONSIDERED

Published Information

"The e-Pesticide Manual", CDS Tomlin, 13th edition, British Crop Protection Council, 2004-05, entry #305.

Studies considered in the Health Risk Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

Not applicable.

B. ADDITIONAL INFORMATION CONSIDERED (in the Water and Air Monitoring Data Assessment)

Published Information

PMRA Document Number	Reference
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Unpublished Information

PMRA Document Number	Reference

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